

**304.17A-162 Identification of sources used to calculate drug product reimbursement -- Process to appeal disputes over maximum allowable cost pricing -- Adjustment of maximum allowable cost and drug product reimbursement -- Duties of pharmacy benefit manager.**

- (1) A pharmacy benefit manager shall:
  - (a) Identify to contracted pharmacies the sources used by the pharmacy benefit manager to calculate the drug product reimbursement paid for covered drugs available under the pharmacy health benefit plan administered by the pharmacy benefit manager; and
  - (b) Establish a process for contracted pharmacies, pharmacy services administration organizations, or group purchasing organizations to appeal and resolve disputes regarding the maximum allowable cost pricing. The process shall include the following provisions:
    1. The right to appeal shall be limited to sixty (60) days following the initial claim;
    2. The appeal shall be investigated and resolved by the pharmacy benefit manager within ten (10) calendar days;
    3. The pharmacy benefit manager shall respond to all appeals in a manner approved by the department;
    4. If the appeal is denied, the pharmacy benefit manager shall provide the reason for the denial and identify the national drug code of a drug product and source where it may be purchased from a licensed wholesaler by contracted pharmacies at a price at or below the maximum allowable cost; and
    5. If an appeal is granted, the provisions of subsection (2) of this section shall apply.
- (2) If a price update is warranted as a result of an appeal granted under subsection (1) of this section, the pharmacy benefit manager shall:
  - (a) Make the change in the maximum allowable cost to the initial date of service the appealed drug was dispensed;
  - (b) Adjust the maximum allowable cost of the drug for the appealing pharmacy and for all other contracted pharmacies in the network of that pharmacy benefit manager that filled a prescription for patients covered under the same health benefit plan to the initial date of service the appealed drug was dispensed;
  - (c) Individually notify all other contracted pharmacies in the network of that pharmacy benefit manager that a retroactive maximum allowable cost adjustment has been made as a result of a granted appeal effective to the initial date of service the appealed drug was dispensed;
  - (d) Adjust the drug product reimbursement for contracted pharmacies that resubmit claims to reflect the adjusted maximum allowable cost if applicable to their contract;

- (e) Allow the appealing pharmacy and all other contracted pharmacies in the network that filled prescriptions for patients covered under the same health benefit plan to reverse and resubmit claims and receive payment based on the adjusted maximum allowable cost from the initial date of service the appealed drug was dispensed; and
  - (f) Make retroactive price adjustments in the next payment cycle.
- (3) For every drug for which the pharmacy benefit manager establishes a maximum allowable cost to determine the drug product reimbursement, the pharmacy benefit manager shall make available to all contracted pharmacies information identifying the national drug pricing compendia or sources used to obtain the drug price data in a manner established by administrative regulations promulgated by the department.
  - (4) For every drug for which the pharmacy benefit manager establishes a maximum allowable cost to determine the drug product reimbursement, the pharmacy benefit manager shall make available to all contracted pharmacies in a manner established by administrative regulations promulgated by the department the comprehensive list of drugs subject to maximum allowable cost and the actual maximum allowable cost for each drug.
  - (5) For every drug for which the pharmacy benefit manager establishes a maximum allowable cost to determine the drug product reimbursement, the pharmacy benefit manager shall make available to the department, upon request, information that is needed to resolve an appeal. If the department is unable to obtain information from the pharmacy benefit manager that is necessary to resolve the appeal, the appeal shall be granted to the appealing pharmacy.
  - (6) For every drug for which the pharmacy benefit manager establishes a maximum allowable cost to determine the drug product reimbursement, the pharmacy benefit manager shall review and make necessary adjustments to the maximum allowable cost for every drug at least every seven (7) calendar days and shall immediately utilize the updated maximum allowable cost in calculating the payments made to all contracted pharmacies.
  - (7) For every drug for which the pharmacy benefit manager establishes a maximum allowable cost to determine the drug product reimbursement, the pharmacy benefit manager shall make available to all contracted pharmacies in a manner established by administrative regulations promulgated by the department weekly updates to the list of drugs subject to maximum allowable cost and the actual maximum allowable cost for each drug.
  - (8) For every drug for which the pharmacy benefit manager establishes a maximum allowable cost to determine the drug product reimbursement, the pharmacy benefit manager shall ensure that drugs subject to maximum allowable costs are:
    - (a) Generally available for purchase by pharmacists and pharmacies in Kentucky from a national or regional wholesaler licensed in Kentucky by the Kentucky Board of Pharmacy;
    - (b) Not obsolete, temporarily unavailable, or listed on a drug shortage list; and
    - (c) 1. Drugs that have an "A" or "B" rating in the most recent version of the

United States Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the Orange Book; or

2. Drugs rated "NR" or "NA" or have a similar rating by a nationally recognized reference.
- (9) For every drug for which the pharmacy benefit manager establishes a maximum allowable cost to determine the drug product reimbursement, the pharmacy benefit manager shall ensure that reimbursement for a drug subject to maximum allowable cost is based solely on that drug and drugs that are therapeutically equivalent if the therapeutically equivalent drugs are listed in the most recent version of the United States Food and Drug Administration Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the Orange Book.
  - (10) For every drug for which the pharmacy benefit manager establishes a maximum allowable cost to determine the drug product reimbursement, the pharmacy benefit manager shall ensure that reimbursement for a "B" rated drug subject to maximum allowable cost is based solely on that drug and drugs that are not therapeutically equivalent to a "B" rating in the most recent version of the United States Food and Drug Administration Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the Orange Book.
  - (11) For every drug for which the pharmacy benefit manager establishes a maximum allowable cost to determine the drug product reimbursement, the pharmacy benefit manager shall ensure that reimbursement for a "NR" or "NA" drug with a similar rating by a nationally recognized reference subject to maximum allowable cost is based solely on that drug and other drugs with a "NR" or "NA" rating or similar rating by a nationally recognized reference that meets criteria for therapeutic equivalence used in the United States Food and Drug Administration Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the Orange Book.
  - (12) For every drug for which the pharmacy benefit manager establishes a maximum allowable cost to determine the drug product reimbursement, the pharmacy benefit manager shall ensure that reimbursement for a drug subject to maximum allowable cost is based solely on that drug if there is no other therapeutically equivalent drug.
  - (13) For every drug for which the pharmacy benefit manager establishes a maximum allowable cost to determine the drug product reimbursement, the pharmacy benefit manager shall ensure that reimbursement for a drug subject to maximum allowable cost is not based on a drug that is obsolete, temporarily unavailable, listed on a drug shortage list, or that cannot be lawfully substituted.

**Effective:** July 15, 2016

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